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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,755	07/03/2001	Peng Cho Tang	038602-1220	1137

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EXAMINER	
WRIGHT, SONYA N	
ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 06/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,755

Applicant(s)

TANG ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are pending in this application.

Election/Restrictions

Applicant's election with traverse of Group IV claims 8-11 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the Examiner has failed to adequately establish that search and examination of the entire application constitutes an undue burden. This is not found persuasive because the inventions in Groups I-IV have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different products and method would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

The generic concept as depicted in claim 8, wherein A is pyrrole; A1, A2, A3, and A4, are carbon; and all other variables are as defined is identified for examination along with the elected embodiment. The remaining subject matter of claims 8-11 and claims 1-7 in their entirety stands withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

The withdrawn subject matter of claims 1-11 properly restricted as said subject matter differs in structure and element from the elected subject matter so as to be patentably distinct therefrom, i.e. a reference which anticipated the elected subject

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matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive.

Claims 8-11 are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified *supra*.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 15, and 16 of U.S. Patent No. 6,313,158 B1, Tang et al.. Although the conflicting claims are not identical, they are not patentably distinct from each other because the prior art claims teach a genus which embraces the instant compounds. See Tang et al. ('158) when R3 is NR8R9, Z is oxygen or sulfur, and all other variables are as defined.

Claims 8-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 22, and 28 of U.S. Patent

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No. 5,792,783, Tang et al.. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims teach a genus which embraces the genus which is taught in the prior art. See Tang et al. ('783) when A is pyrrole, and all other variables are as defined.

Claims 8 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6,395,734 Tang et al.. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims teach a genus which embraces the genus which is taught in the prior art. See Tang et al. ('734) when R1-R10 in claim 1 are as defined. The definition of variable R5 is missing from claim 1 of '734. The specification defines R5 to be the same as R3, R4, and R6, and it can be assumed that R5 should also be the same as R3, R4, and R6 in the patent claims.

Claims 8 and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 16 of copending Application No. 09/762,198. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims teach a genus which embraces the genus which is taught in '198. See '198 when all variables are as defined except that all heteroalicyclic groups and heteroaryl groups are omitted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The copending claims are drawn to a specific combination of R8, R9, and R10, with specific subgeneric combinations in '783 and '734, while the claims of '158 claimed all variations to be equivalent at all positions.

One having ordinary skill in the art would find the claims prima facie obvious since the instant subgenus and the issued subgenus are all within the claimed equivalency of '158.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claim is directed to "metabolites, esters, amides and prodrugs thereof". The terms "esters and metabolites" lack description in the specification. Applicant has not described any "metabolites" or "esters". Thus, one does not know what is actually being covered by said terms. There is no description of what substituents are to be substituted on the indole ring and the pyrrole ring in order to prepare an "ester" or "metabolite".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim , is vague and indefinite because of the terms "metabolites, esters, amides, and prodrugs". The specification only briefly describes "amides" and "prodrugs". There is no indication in the specification as to what is intended by the expressions "metabolites, and esters", i.e. there is no definition as to what is contemplated by said expressions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Celia Chang

Primary Examiner

Group 1600

Sonya Wright

June 11, 2002